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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,448	01/04/2001	Susan I. Shelso	06530.0275	3427

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EXAMINER

LANDREM, KAMRIN R

ART UNIT	PAPER NUMBER
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3738

14

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/753,448

Applicant(s)

SHELSON, SUSAN I.

Examiner

Kamrin R. Landrem

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 25, 2003 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-11, 13, 15-21, 23, 24, 28-30, 32, 33, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ravenscroft (USPN 5,702,418).

With reference to Figure 1, Ravenscroft discloses a delivery system 10 comprising a catheter 11 having self-expanding (10:49) stent 20 disposed on distal end near loading funnel 13. Figure 1 shows that loading funnel 13 is used to compress stent 20 on the distal end of catheter 11 within an outer member 24 during delivery into the patient's body. The catheter 11 further comprises a guidewire 31 and a tubular member 17 comprising at least three radiopaque marker bands 37 that indicate the leading, middle, and trailing ends of stent 20. The catheter also has an outer member 24 that is slidable relative to the tubular member (5:15-22) and is configured to

Art Unit: 3738

retain the stent 20 in a radially compressed position. In one embodiment Ravenscroft discloses an inflatable balloon device 60 disposed on the catheter beneath the stent (7:10-13). The marker bands can be used to indicate a position corresponding to the re-constrain limit of a partially deployed stent (7:53-59). Ravenscroft also discloses the method for implanting a self-expanding stent comprising the following steps; providing the stent/deployment system combination, delivering the system to the target region, partially deploying the stent, re-constraining the stent, and inflating the balloon device to assist the expansion of the stent (6:21-58 and 7:1-41).

Claims 31,36-39,41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by St. Germain et al (USPN 5,534,007).

St. Germain et al discloses a delivery system 5 for a self-expanding stent comprising a catheter 5 having a tubular member with an inflatable balloon disposed beneath a self-expandable stent 35 and a loading funnel 25 disposed on its distal end. The catheter also includes a holding sleeve 60 and an outer member 40 that is slidable relative to the tubular member (3:26-59). The loading funnel is capable of assisting with compression of the stent by fixing it in place in the axial direction. The tubular member defines a first lumen 15 for guidewire 20 and second lumen for providing a fluid passage (3:57-59).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8,12,14,22,25,26,27, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft in view of St. Germain et al.

Ravenscroft, as discussed above, discloses the stent delivery device as claimed. Ravenscroft however fails to teach the inflation means for the inflatable balloon device 60 disposed on the catheter beneath the stent (7:10-13) and a holding sleeve configured to hold the self-expanding stent. St. Germain teaches a stent delivery device comprising a catheter 5 having a tubular member with an inflatable balloon disposed beneath a self-expandable stent 35 a first lumen 15 for guidewire 20 and second lumen for providing a fluid passage (3:57-59), and a holding sleeve 60 for maintaining the position of the compressed stent. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the delivery system of Ravenscroft with the inflation means and holding sleeve as disclosed by St. Germain in order to inflate the balloon and to maintain appropriate stent positioning within the catheter.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain in view of Ravenscroft.

Art Unit: 3738

St. Germain as discussed above, discloses the delivery system as claimed however St. Germain fails to disclose three marker bands and their locations relative to the stent. Ravenscroft discloses a catheter 11 further comprises a guidewire 31 and a tubular member 17 comprising at least three radiopaque marker bands 37 that indicate the leading, middle, and trailing ends of stent 20 that ensure proper positioning of the stent within the patient (6:21-58 and 7:1-41). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the delivery system as disclosed by St. Germain by incorporating the three marker bands as taught by Ravenscroft to enable to appropriately position the stent within the patient's vessel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

KRL

Kamrin Landrem
Examiner
AU 3738



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700